



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0007]

Biosimilar User Fee Rates for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development, certain applications and supplements for approval of biosimilar biological products, establishments where approved biosimilar biological product products are made, and biosimilar biological products after approval.

BsUFA directs FDA to establish, before the beginning of each fiscal year, the initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application, establishment, and product fees. These fees are effective on October 1, 2014, and will remain in effect through September 30, 2015.

FOR FURTHER INFORMATION CONTACT: Rachel Richter, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14216, Silver Spring, MD 20993-0002, 301-796-7111.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j-51, 379j-52, and 379j-53), as added by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144), establish fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application, or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning in the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD program.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the BPD program. The sponsor must pay the reactivation fee by the earlier of the following dates: no later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product; or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application. Annual BPD fees will be due beginning for the fiscal year after the year in which the reactivation fee was paid.

BsUFA also establishes fees for certain types of applications and supplements, establishments where approved biosimilar biological products are made, and biosimilar biological products post-approval (section 744H(a)(2), 744H(a)(3) and 744H(a)(4), respectively, of the FD&C Act). When certain conditions are met, FDA may grant small businesses a waiver from the biosimilar biological product application fee (section 744H(c)(1) of the FD&C Act).

Under BsUFA, the initial and annual BPD fee rates for a fiscal year are equal to 10 percent of the fee rate established under the Prescription Drug User Fee Act (PDUFA) for an application requiring clinical data for that fiscal year. The reactivation fee is equal to 20 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year. Finally, the application, establishment, and product fee rates under BsUFA are equal to the application, establishment, and product fee rates under PDUFA, respectively.

II. Fee Amounts for FY 2015

BsUFA directs FDA to establish the biosimilar biological product fee rates in each fiscal year by reference to the user fees established under PDUFA for that fiscal year. For more information about BsUFA, please refer to the FDA Web site at <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm>. PDUFA fee calculations for FY 2015 are published elsewhere in this issue of the Federal Register. The BsUFA fee calculations for FY 2015 are described in this document.

A. Initial and Annual BPD Fees; Reactivation Fees

Under BsUFA, the initial and annual BPD fees equal 10 percent of the PDUFA fee for an application requiring clinical data, and the reactivation fee equals 20 percent of the PDUFA fee for an application requiring clinical data. The FY 2015 fee for an application requiring clinical data under PDUFA is \$2,335,200. Multiplying the PDUFA application fee, \$2,335,200, by 0.1

results in FY 2015 initial and annual BPD fees of \$233,520. Multiplying the PDUFA application fee, \$2,335,200, by 0.2 results in an FY 2015 reactivation fee of \$467,040.

B. Application and Supplement Fees

The FY 2015 fee for a biosimilar biological product application requiring clinical data equals the PDUFA fee for an application requiring clinical data, \$2,335,200. The FY 2015 fee for a biosimilar biological product application not requiring clinical data equals half this amount, \$1,167,600. However, under section 744H(a)(2)(A) of the FD&C Act, if a sponsor that submits a biosimilar biological product application has previously paid an initial BPD fee, annual BPD fee(s), and/or reactivation fee(s) for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees. The FY 2015 fee for a biosimilar biological product supplement with clinical data is \$1,167,600, which is half the fee for a biosimilar biological product application requiring clinical data.

C. Establishment Fee

The FY 2015 biosimilar biological product establishment fee is equal to the FY 2015 PDUFA establishment fee of \$569,200.

D. Product Fee

The FY 2015 biosimilar biological product fee is equal to the FY 2015 PDUFA product fee of \$110,370.

III. Fee Schedule for FY 2015

The fee rates for FY 2015 are provided in Table 1.

Table 1.--Fee Schedule for FY 2015

Fee Category	Fee Rates for FY 2015
Initial BPD	\$233,520
Annual BPD	\$233,520
Reactivation	\$467,040
Applications ¹	

Requiring clinical data	\$2,335,200
Not requiring clinical data	\$1,167,600
Supplement requiring clinical data	\$1,167,600
Establishment	\$569,200
Product	\$110,370

¹ Under section 744H(a)(2)(A) of the FD&C Act, if a sponsor that submits a biosimilar biological product application has previously paid initial BPD fees, annual BPD fees, and/or reactivation fees for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees.

IV. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, Application, and Supplement Fees

The fees established in the new fee schedule are effective October 1, 2014. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product, or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program must pay the reactivation fee by the earlier of the following dates: no later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product; or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application.

The application or supplement fee for a biosimilar biological product is due upon submission of the application or supplement.

To make a payment of the initial BPD, reactivation, supplement, or application fee, you must complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (<http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm>) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer.

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after completing the Biosimilar User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order, and make it payable to the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. If you prefer to send a check by courier such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact U.S. Bank at 314-418-4013 if you have any questions concerning courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD, 20993-0002.

The tax identification number of FDA is 53-0196965.

B. Annual BPD, Establishment, and Product Fees

FDA will issue invoices for annual BPD, biosimilar biological product establishment, and biosimilar biological product fees under the new fee schedule in August 2014. Payment instructions will be included in the invoices. Payment will be due on October 1, 2014. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2014, FDA will issue invoices in November 2014 to firms subject to fees for FY 2015 that qualify for the BPD fee after the August 2014 billing. FDA will issue invoices in November 2015 for any annual products and establishments subject to fees for FY 2015 that qualify for fee assessments after the August 2014 billing.

Dated: July 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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